

Appl. No. 10/549,389  
Reply to Office Action mailed January 5, 2007

R E M A R K S

The Examiner is respectfully requested to acknowledge receipt of the certified copy of the priority document.

The Office Action enclosed copies of the INFORMATION DISCLOSURE STATEMENTS BY APPLICANT Form PTO/SB/08B dated September 14, 2005 and Form PTO/SB/08B dated October 24, 2005, with the Examiner's initials in the left column next to some of the cited publications, indicating that each of the initialed cited publications was considered and made of record. On the Form PTO/SB/08B dated September 14, 2005, the Examiner drew a line through the NAKAGAWA and the KANAOKA et al. publications. NAKAGAWA and KANAOKA et al. are Japanese language publications.

On the enclosed copy of the Form PTO/SB/08B dated September 14, 2005, next to the NAKAGAWA publication, the following was typed: "English translation not provided," and next to the KANAOKA et al. publication, the following was typed: "Translation provided does not have complete citation and it is not certified."

For the following reasons, it is respectfully submitted that the Examiner return to the undersigned a copy of the Form

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PTO/SB/08B dated September 14, 2005, with the Examiner's initials next to each of the cited publications, including the NAKAGAWA and KANAOKA et al. publications, to indicate that all the cited publications were considered and made of record.

The NAKAGAWA and KANAOKA et al. publications were both cited in the copy of the English-language International Search Report, which was filed on September 14, 2005. This should have been sufficient for the Examiner to consider and make of record the NAKAGAWA and KANAOKA et al. publications, as seen in the following quoted excerpt from MPEP 609.04(a)III:

"Where the information listed is not in the English language, but was cited in a search report or other action by a foreign patent office in a counterpart foreign application, the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office. This may be an explanation of which portion of the reference is particularly relevant, to which claims it applied, or merely an 'X', 'Y', or 'A' indication on a search report."  
[emphasis provided]

Enclosed herewith is an executed DECLARATION OF ACCURACY OF TRANSLATION FOR KANAOKA ET AL. PUBLICATION dated May 2, 2007,

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which provides the certified complete citation of the KANAOKA et al. publication requested by the Examiner.

Regarding item no. 2 at the bottom of page 2 of the Office Action, under the heading "Priority," enclosed herewith is an English-language translation of applicant's priority application, along with a DECLARATION OF ACCURACY OF TRANSLATION of OTOYA SUZUKI dated April 26, 2007.

Claim 1 was editorially revised and was amended to replace "comprising" with --consisting essentially of--.

Claim 5 was amended into independent form by including the features of claim 1.

New claim 13 is supported on page 3, line 17 of the specification.

New claim 14 is supported in the specification on page 8, lines 21 to 24.

New claim 15 is supported in the specification on page 8, line 23 and lines 18 to 29.

New claim 16 is supported in the specification on page 8, last two lines.

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New claim 17 is supported in the specification on page 5, lines 34 to 25.

New claim 18 is supported in the specification on page 5, lines 27 to 30.

New claim 19 is supported in the specification on page 5, lines 30 to 33.

New claim 20 includes the features of claims 17 to 19.

Claims 1 to 5 were rejected under 35 USC 102 as being anticipated by Alexander and Raicht (1998), Digestive Diseases and Sciences, Vol. 43, No. 12, pp. 2652-2658, as evidenced by Ultrapsec™ -II RNA, Isolation System, Biotechx Bulletin, No. 28, 1993, for the reasons stated in item no. 5 on pages 3 to 5 of the Office Action.

The Alexander and Raicht publication is discussed on page 2, lines 19 to 33 of the present specification.

Alexander and Raicht (1998) disclose a method for preparing a sample to extract RNA comprising a step for separating cell components by using centrifugation (page 2653, left-hand column, lines 5 to 1 from the bottom).

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In contrast to Alexander and Raicht, applicant's claims are directed to a method for preparing a sample to extract RNA without separating cell components by centrifugation.

Applicant's claims 1 to 5 are thus substantially different from Alexander and Raicht.

Withdrawal of the 35 USC 102 rejection is therefore respectfully requested.

Claim 6 was rejected under 35 USC 103 as being unpatentable over Alexander and Raicht (1998), Digestive Diseases and Sciences, Vol. 43, No. 12, pp. 2652-2658, as evidenced by Ultraspec™ -II RNA, Isolation system, Biotechx Bulletin, No. 28, 1993, in view of Sano et al., (1995), Cancer Research, 55: 3785-3879 for the reasons set forth in item no. 7 on pages 5 to 6 of the Office Action.

It was admitted in the Office Action that Alexander and Raicht do not teach that the tumor marker is COX-2.

Alexander and Raicht do not teach or suggest the method of applicant's claim 1. As discussed above, Alexander and Raicht do not teach or suggest that the tumor marker is COX-2.

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Further, as seen in the Example 2 of the present specification, since no PCR products were obtained from the sample obtained by using the method of Alexander and Raicht comprising a step for separating cell components, the method of Alexander and Raicht is not useful for the detection of the COX-2 tumor marker (see page 10, lines 2 to 31 of the present specification).

Since it is well-known to those of ordinary skill in the art that RNA is very sensitive to RNase, it is considered that extracting RNA directly from a biological sample containing an enormous amount of RNases would not be possible and that a step for separating cell components prior to extracting RNA is essential.

Therefore, it is respectfully submitted that one of ordinary skill in the art at the time of the invention would not consider removing the step for separating cell components from the method of Alexander and Raicht.

Withdrawal of the 35 USC 103 rejection is therefore respectfully requested.

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In summary, it is respectfully submitted that applicant's claims are not anticipated and are not rendered obvious over the references, either singly or combined in the manner relied upon in the Office Action, in view of the distinctions discussed hereinabove. It is furthermore submitted that there are no teachings in the references to combine them in the manner relied upon in the Office Action.

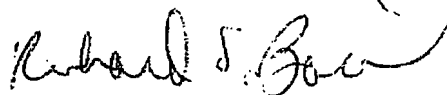
An INFORMATION DISCLOSURE STATEMENT is being filed concomitantly herewith.

Reconsideration is requested. Allowance is solicited.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

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& Chick, P.C.  
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RSB/ddf

Respectfully submitted,



Richard S. Barth  
Reg. No. 28,180

- Encs.: (1) PETITION FOR EXTENSION OF TIME  
(2) English-language translation of applicant's priority document, along with a DECLARATION OF ACCURACY OF TRANSLATION of OTOYA SUZUKI dated April 26, 2007  
(3) DECLARATION OF ACCURACY OF TRANSLATION FOR KANAOKA ET AL. PUBLICATION dated May 2, 2007  
(4) INFORMATION DISCLOSURE STATEMENT

**COPY**

DOCKET NO.: 05596/HG - Shigeru KANAOKA  
SERIAL NO.: 10/549,389

AMD...1.111; EXT. OF TIME & FORM PTO-2038 FOR \$60 &  
ENG.-LANG. TRANS. OF APPLICANT'S PRIORITY DOCUMENT,  
ALONG WITH DEC. OF ACCURACY OF TRANS. of Otoyasu SUZUKI dated  
April 28, 2007; DECL. OF ACCURACY OF TRANS. FOR KANAOKA  
ET AL. PUBL. DATED MAY 2, 2007;  
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EXPRESS MAIL LABEL: EV 922 753 695 US  
DATE OF DEPOSIT: MAY 4, 2007  
DUE: MAY 5, 2007 (SATURDAY), THEREFORE  
DUE: MAY 7, 2007 (MONDAY)

RSB/ddf

